IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MISSOURI
WESTERN DIVISION

NATUROPATHIC LABORATORIES INTERNATIONAL, INC.,	)	
Plaintiff,	)	
vs.	)	**Case No. 02-0604-CV-W-GAF**
DERMAL RESEARCH LABORATORIES, INC.,	)	
Defendant.	)	

ORDER

Presently before the Court is a Motion for Judgment as a Matter of Law ("JMOL") or Alternatively for a New Trial filed by Plaintiff/Counterclaim Defendant, Naturopathic Laboratories International, Inc. ("Naturopathic"). (Doc. 213). Naturopathic argues that Defendant/Counterclaim Plaintiff, Dermal Research Laboratories, Inc. ("Dermal"), presented no legally sufficient basis from which a jury could find that Naturopathic infringed United States Patent 5,888,984 ("the '984 patent"), that the infringement was willful, and that Dermal is entitled to damages in the amount of $1,902,173.40. (Doc. 226). Dermal opposes this Motion, arguing that Naturopathic's arguments have been waived, and even if Naturopathic's arguments have not been waived, Dermal presented sufficient evidence to support the jury's verdict. (Doc. 239). For the reasons set forth more completely below, Naturopathic's Motion for Judgment as a Matter of Law is GRANTED.

DISCUSSION

I. Facts

This case arises out of Naturopathic's alleged infringement of Dermal's '984 patent. In the initial complaint, filed June 21, 2002, Naturopathic sought declaratory judgment on non-infringement and invalidity of the '984 Patent. (Doc. 1). On July 31, 2002, Dermal filed its answer and asserted a counterclaim for patent infringement of the '984 Patent against Naturopathic. (Doc. 8). On June 1, 2005, this Court denied the parties' cross motions for summary judgment. (Doc. 169). The case was tried before a jury between June 13 and June 17, 2005. Ultimately, the jury found that Naturopathic infringed Dermal's patent, that the infringement was willful, and that Dermal was entitled to damages in the amount of $1,902,173.40. (Doc. 208).

The official title of the '984 Patent is "Pharmaceutical Composition of Complex Carbohydrates and Essential Oils and Methods of Using the Same." The application for the '984 Patent was filed on May 12, 1994 and was issued on March 30, 1999. Drs. Harold and Karen Brown invented the '984 Patent and it is currently owned by Dermal. The '984 Patent has sixty-five claims, seven independent and fifty-eight dependent. The only claim at issue, Claim 1, has been construed as:

> A topical pharmaceutical composition which comprises as an active ingredient a pharmacologically effective amount of at least one low purity or cosmetic grade complex carbohydrate selected from the group consisting of oligosaccharides, sialylated oligosaccharides, polysaccharides and glycosaminoglycans, and at least one essential oil in an amount effective to allow penetration of the dermis of mammals by the complex carbohydrate.

(Doc. 80, Claim Construction Order of '984 Patent).

The Court has construed the limitations of Claim 1, in relevant part, as follows:

> "Active" means producing an intended action or effect: active ingredients.
> "Pharmacologically effective" means an amount that is medically effective.

> "Complex carbohydrates" means a polymer comprising more than two sugar moieties, such as heparin, hyaluronic acid, chondroitin sulfate[1], dermatan sulfate, keratan sulfate and acemannan, for example.
> "Amount effective" means a quantity that produces a result.
> "Allow penetration of the dermis of mammals by the complex carbohydrate" means the combination of the complex carbohydrate and the essential oil produces a treatment effect by the complex carbohydrate. That treatment effect is pain relief.
> "Dermis" means the sensitive connective tissue layer of the skin located below the epidermis, containing nerve endings, sweat and sebaceous glands, and blood and lymph vessels.

In its Order denying summary judgment, the Court made clear that it was encumbent upon Dermal to show at trial that chondroitin sulfate, when topically applied, independently relieves pain, and also to show that there was a sufficient amount of chondroitin sulfate in the accused Joint-Ritis[2] products to do so. The Court stated, "...the determination of chondroitin sulfate as an active ingredient in Joint-Ritis is absolutely essential to the survival of Dermal's claim for infringement." (Doc. 169). The Court further explained that Dermal must show that the pain relief experienced by users of Joint-Ritis is the result of the chondroitin sulfate acting alone, not the result of the chondroitin sulfate working in combination with other ingredients such as glucosamine. Id.

Accordingly, the Court instructed the jury that, to prevail on its infringement claim, Dermal must prove by a preponderance of the evidence that the chondroitin sulfate in the Joint-Ritis products is an

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[1]Chondroitin sulfate is the complex carbohydrate at issue in this case.

[2]Naturopathic's Joint-Ritis products are topical pharmaceutical compositions manufactured for the treatment of arthritis pain. Naturopathic has sold Joint-Ritis as an arthritis pain relief formulation in both a pump and roll-on form since 1999. The formulation for Joint-Ritis was issued U.S. Patent No. 6,482,401("the '401 Patent") on November 19, 2002. The application for the '401 Patent was filed on October 1, 1999. Jan Knigge ("Knigge") is the developer and the sole named inventor of the '401 Patent. Naturopathic is the assignee and current owner of the '401 Patent.

"active" ingredient present in "pharmacologically effective amounts." (Doc. 202). The Court further instructed the jury that it must find that the chondroitin sulfate in Joint-Ritis provides "pain relief independently of any pain relief which may be provided by other ingredients such as the glucosamine or menthol, or by a combination of chondroitin sulfate and other ingredients such as the glucosamine or menthol." Id. The jury ultimately found that the chondroitin sulfate contained in the Joint-Ritis products was an "active" ingredient and was present in "pharmacologically effective" amounts. (Doc. 208). The jury also found that Naturopathic's infringement of Dermal's patent was willful, and awarded damages in the amount of $1,902,173.40. Id.

In its present Motion, Naturopathic argues that Dermal presented no legally sufficient evidence at trial from which a jury could find that Naturopathic infringed the '984 patent, that the infringement was willful, and that Dermal was entitled to damages in the amount of $1,902,173.40. (Doc. 226). Dermal argues that Naturopathic's arguments have been waived and are not properly before the Court. (Doc. 239). Dermal further argues that, even if Naturopathic's arguments have not been waived, Dermal presented sufficient evidence to support the jury's verdict. Id.

II. Standard

Fed. R. Civ. P. 50(a) governs the granting of a JMOL and provides, in relevant part:

> [I]f during a trial by jury a party has been fully heard on an issue and there is no legally sufficient evidentiary basis for a reasonable jury to find for that party on that issue, the court may determine the issue against that party and may grant a motion for judgment as a matter of law against that party with respect to a claim or defense that cannot under the controlling law be maintained or defeated without a favorable finding on that issue.

Fed. R. Civ. P. 50(b) further provides, in relevant part:

> [I]f, for any reason, the court does not grant a motion for judgment as a matter of law made at the close of all the evidence, the court is considered to have submitted the action to the jury subject to the court's later deciding the legal questions raised by the motion.

Naturopathic is entitled to a JMOL if there were no "probative facts" offered at trial that support the jury's conclusion that the chondroitin sulfate in Joint-Ritis is an active ingredient present in pharmacologically effective amounts to independently effect pain relief. *See* Shepard v. Wapello County, Iowa, 303 F.Supp.2d 1004, 1006 (S.D. Iowa 2003) (internal quotations omitted). In ruling on a motion for JMOL, "the Court must view all evidence in the light most favorable to the non-moving party and draw all reasonable inferences in favor of that party." Wahpeton Canvas Co. v. Frontier, Inc., 870 F.2d 1546, 1551 (Fed. Cir. 1989) (applying Eighth Circuit law). However, "[a] mere scintilla of evidence is inadequate to support a verdict," and JMOL is proper when the record contains no proof beyond speculation to support a verdict. Larson by Larson v. Miller, 76 F.3d 1446, 1452 (8th Cir. 1996) (citations omitted).

III. Analysis

A. Naturopathic's Oral Motion for JMOL

Dermal argues that Naturopathic waived its right to seek relief under Rule 50(b) because, although Naturopathic moved for a JMOL after Dermal rested its case, Naturopathic did not renew its motion at the close of the evidence. (Doc. 239). A pre-verdict JMOL motion at the close of all the evidence is a prerequisite to filing a renewed JMOL motion under Rule 50(b). *See* Mathieu v. Gopher News Co., 273 F.3d 769, 776 (8th Cir. 2001); Pulla v. Amoco Oil Co., 72 F.3d 648, 655 (8th Cir. 1995).

Naturopathic argues that there was no need to "renew" its motion because the Court had not yet ruled on the motion for JMOL that Naturopathic made at the close of Dermal's evidence. (Doc. 243). In support of its argument, Naturopathic directs the Court to the portion of the trial transcript where

Naturopathic made its oral motion for a JMOL at the close of Dermal's evidence.[3] After Naturopathic made its motion, the Court stated:

> THE COURT: [Mr. Brown] [y]ou can respond to that if you want to. I do have some concern in that regard but it's my intention to let the jury decide the case and then I am going to overrule the motion. But do you want to speak, given that do you want to say anything?
> MR. BROWN: Your Honor, if the record is preserved in that regard then that's fine.

(Trial Tr. 556: 8-14). Naturopathic's counsel submits that there was an error in the transcription of this portion of the record, and that the Court said, "it's my intention to let the jury decide the case and then I am going to **rule on** the motion," not "**overrule** the motion." Naturopathic posits that the Court was going to let the case go to the jury and Naturopathic's motion stood unresolved with the opportunity to be briefed, if necessary, after the verdict. Therefore, Naturopathic argues, oral "renewal" of the motion at the close of all evidence was not necessary because the motion was still pending.

The Court agrees with Naturopathic that the motion stood unresolved and renewal of the motion at the close of the evidence was not necessary. Whether the transcript contained an error or the Court simply misspoke, it was the Court's intention and at the time understood by the parties that Naturopathic's oral motion for a JMOL be preserved. In addition, after the verdict, the following exchange reflects that counsel understood that Naturopathic's oral motion for a JMOL had been preserved:

> THE COURT:...There we have it and that concludes our business in this case, at least for the time being...
> MR. SCHWAB: On the JNOV motions do you have a Schedule.
> THE COURT: I don't really know what the rules provide.

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[3]Naturopathic's Motion urged that Dermal had not presented a *prima facie* case of infringement because it failed to offer evidence proving that the chondroitin sulfate present in the Joint-Ritis products was active and present in a pharmacologically effective amount to effect pain relief.

MR. SCHWAB: If it's within the rules.

THE COURT: If it's within the rules and if you need additional time for that I certainly would consider that and grant you a reasonable extension if necessary.

MR. BROWN: I think it's 30 days for the JNOV.

MR. SCHWAB: We will check it out.

THE COURT: All right. Thank you all.

(Trial Tr. 719: 24-720: 13). Because it was the Court's intention and the parties' understanding that Naturopathic's oral motion for JMOL was preserved, the Court finds that Naturopathic has not waived its right to seek relief under Rule 50(b).

B. Sufficiency of the Evidence

Naturopathic argues that Dermal offered no probative facts that support the jury's conclusion that the chondroitin sulfate in Joint-Ritis is an "active ingredient" that is present in "pharmacologically effective" amounts to independently relieve pain. (Doc. 226). In support of its argument, Naturopathic directs the Court to the testimony of Dermal's witnesses, arguing that none of the witnesses provided sufficient evidence to satisfy Dermal's burden of proving that the chondroitin sulfate in Joint-Ritis products alone is an "active" ingredient which is "pharmacologically effective" for pain relief when topically applied. (Doc. 226, 243). Naturopathic also notes that none of its own witnesses provided sufficient evidence to satisfy Dermal's burden of proof. Id. Indeed, the Court finds that the record is devoid of evidence isolating the pain relieving effect of the chondroitin sulfate in the Joint-Ritis products.

"When an expert opinion is not supported by sufficient facts to validate it in the eyes of the law...it cannot support the jury's verdict." Brook Group Ltd. v. Brown & Williamson Tobacco, 509 U.S. 209, 242 (U.S. 1993) ; *see also* Concord Boat Corp. v. Brunswick Corp., 207 F.3d 1039, 1057 (8th Cir. 2000);

Morgenstern v. Wilson, 29 F.3d 1291, 1297 (8th Cir. 1994). In the instant case, none of the witnesses provided any facts or evidence to support the jury's verdict of infringement.[4]

1. Dr. Potts

Dermal argues that its expert, Dr. Russell Potts ("Dr. Potts"), provided sufficient evidence to support the jury's verdict. (Doc. 239). In support of its argument, Dermal directs the Court to Dr. Potts' testimony that chondroitin sulfate has been shown in peer reviewed publications to be capable of being delivered through the skin, and that chondroitin sulfate produces a medicinal effect so long as it gets into the body. (Trial Tr. 429: 9-430:8). Dr. Potts testified that the amount of chondroitin sulfate in the accused Joint-Ritis products is .375%. (Trial Tr. 424:17). Dr. Potts then opined that using synthetic membranes to simulate the skin demonstrated that the ingredients in the Joint-Ritis products would penetrate the skin. (Trial Tr. 431:1-9).

However, to the extent Dr. Potts studied the accused Joint-Ritis products, the tests he undertook with Dr. Karen Brown ("Dr. Brown") were designed only to determine whether the various ingredients in the accused Joint-Ritis products passed through the synthetic membrane. (Trial Tr. 438:4-15). The test did not evaluate whether the chondroitin sulfate in the Joint-Ritis products was present in a pharmacologically effective amount to relieve pain. Id.

Apart from his testimony that the ingredients in Joint-Ritis are capable of entering the body through the skin, the only specific evidence upon which Dr. Potts relied to support his conclusion that the chondroitin

[4]Because this Court finds that Dermal presented no legally sufficient basis for the jury to find that Naturopathic infringed the '984 patent, the Court will not address the jury's finding that the infringement was willful or the award of damages.

sulfate in the Joint-Ritis products is present in pharmacologically effective amounts to relieve pain was a 2003 study conducted by Australian researchers. (Dermal Trial Ex. 53) ("Australian Study"). The Australian study, however, observed only the effect of a combination of glucosamine[5] and chondroitin sulfate at much higher concentrations than present in the accused Joint-Ritis products. The Australian study did not separate the effects of the glucosamine and the chondroitin sulfate and only considered their combined activity. Moreover, the Australian study postulates that additional pain relief was likely the consequence of the glucosamine, and that the chondroitin acted as a carrier. (Dermal Trial Ex. 53 at 523). Dr. Potts admitted that the Australian study did not determine that chondroitin sulfate alone relieves pain. (Trial Tr. 464: 2-8).

> Q: ...that test never took the chondroitin sulfate alone, carved it out, said here it is, work with the essential oil. It worked it in a combination with glucosamine, right?
> A: In that study, that's correct.

Viewing the evidence in the light most favorable to Dermal, a jury could conclude from Dr. Potts' testimony that the various ingredients in Joint-Ritis can be absorbed into the body through the skin and that chondroitin sulfate can act as a pain reliever when combined with glucosamine. However, Dr. Potts simply provided no facts or evidence isolating the pain relieving effect of chondroitin sulfate in the amount present in the Joint-Ritis products or even isolating the pain relieving effect of chondroitin sulfate alone. No reasonable juror could conclude from Dr. Potts' testimony that a sufficient amount of chondroitin sulfate exists in Joint-Ritis products to independently provide pain relief. Accordingly, Dr. Potts' testimony did not provide a sufficient basis to support the jury's verdict of infringement.

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[5]Glucosamine is not a complex carbohydrate. Joint-Ritis products also contain glucosamine.

2. Dr. Brown

Similarly, Dr. Brown provided no evidence upon which a jury could find that the chondroitin sulfate in Joint-Ritis products is an "active ingredient" that is "pharmacologically effective" for pain relief when topically applied. Dermal argues that Dr. Brown's testimony is sufficient to support the jury's verdict because she testified that chondroitin sulfate is active and can produce a treatment effect. (*See* Trial Tr. 260: 23-261:3; 263: 3-20). However, Dr. Brown did not test the accused Joint-Ritis products or any other product with the same levels of menthol or chondroitin sulfate. Indeed, Dr. Brown admitted that, other than rubbing the accused Joint-Ritis products on her skin, she did not perform any tests of the Joint-Ritis products that measured the pain-relieving effect of the chondroitin sulfate, nor was she able to identify a test performed by anyone that measured it:.

> Q: So you rely on the testing in your notebook, no specific testing on the Joint-Ritis Products themselves?
> A: No, I mean yes, I am saying I have not done thorough testing on Joint-Ritis, if that's what you're asking.

(Trial Tr. 316: 20-24; 318: 10-12; 322: 23-323: 2). Dr. Brown also testified that, in one study, "people reported a better effect with a combination of chondroitin sulfate and hyaluronic acid than with hyaluronic acid alone." (Trial Tr. 273: 7-11). However, Dr. Brown's testimony that the *combination* of chondroitin sulfate and hyaluronic acid worked better than hyaluronic acid alone is not evidence that chondroitin sulfate alone is an active pain reliever, or that the chondroitin sulfate in the accused Joint-Ritis products is present in "pharmacologically effective" amounts.

Further, the only anecdotal report in the '984 Patent in which chondroitin sulfate was the only complex carbohydrate in the combination was an account of an incomplete treatment conducted by a third

party on an Alzheimer's patient. (Dermal Trial Ex. 1) ("'984 Patent Example 8"). Dr. Brown testified that '984 Patent Example 8 "...tested chondroitin sulfate alone with essential oil." (Trial Tr. 275: 10-12). She admitted, however, that the description of the test mentioned nothing concerning pain relief:

> Q: If you look at your reporting concerning Example 8 in the patent, is there any mention at all in the patent concerning Example 8 of pain relief?
> A: It does not specifically direct pain relief, no.

(Trial Tr. 317: 22-25). Although Dr. Brown testified that "the combination did have an effect, it reduced the pain and actually healed the bedsores," (Trial. Tr. 276: 7-8), there is no report of pain relief from the patient or the person who applied the product.

Even if the jury believed Dr. Brown's conclusory testimony that chondroitin sulfate alone relieves pain, Dr. Brown offered no facts or evidence isolating the pain relieving effect of chondroitin sulfate in the amounts present in the accused Joint-Ritis products. Like Dr. Potts, Dr. Brown's testimony simply did not provide a legally sufficient basis for the jury's verdict of infringement.

3. Naturopathic's Evidence

Dermal argues that, in addition to the testimony of its own witnesses, Naturopathic offered evidence sufficient to support the jury's verdict. Dermal argues that Naturopathic's witnesses, David Steinberg ("Steinberg") and Knigge, admitted that chondroitin sulfate has pain reducing effects. (Trial Tr. 610: 18-611:25). Dermal also argues that Naturopathic's own testing, which compared Joint-Ritis with another Naturopathic product, Nature's Chemist, revealed that chondroitin sulfate is present in "pharmacologically effective" amounts in the accused Joint-Ritis products to act as an independent pain reliever.

Steinberg did not admit that the chondroitin sulfate in Joint-Ritis is an "active ingredient" that is present in "pharmacologically effective" amounts to act as a pain reliever when topically applied. At most,

Steinberg agreed that chondroitin sulfate acts as an anti-inflammatory *when used as a dietary supplement*. (Trial Tr. 610:18-612:13). Knigge also did not testify that the chondroitin sulfate in the Joint-Ritis products an "active ingredient" that is present in "pharmacologically effective" amounts to act as a pain reliever. Rather, Knigge simply agreed that, when taken orally over a period of time, research showed chondroitin sulfate could be beneficial for the repair of connective tissue. (Knigge Trial Depo. 18:23-19:14; 19:24-20:13; 22:5-19). Moreover, Knigge testified that menthol was the "active ingredient" in Joint-Ritis, and that the combination of chondroitin sulfate and glucosamine simply allowed the menthol to remain on the skin for a longer period of time, thereby facilitating the pain relieving effects of the menthol. (Knigge Trial Depo. 24:3-24).

Naturopathic conducted its own testing on Joint-Ritis products, which involved comparison with another of Naturopathic's products, Nature's Chemist. Nature's Chemist contains extra lanolin (a skin moisturizer) instead of chondroitin sulfate and glucosamine. (Trial Tr. 554: 9-14). Naturopathic's testing of the Joint-Ritis products yielded "unexpected pain relief." (Trial Tr. 543-545). However, like the tests performed by Dermal's experts, Naturopathic's testing did not isolate or measure whether the chondroitin sulfate was active as a pain reliever independently of the glucosamine or the menthol, or whether the chondroitin sulfate was present in "pharmacologically effective" amounts in the Joint-Ritis products. Rather, Naturopathic's testing only considered the combined activity of the chondroitin sulfate and the other ingredients in Joint-Ritis products.

At best, Naturopathic's evidence supports the conclusion that chondroitin sulfate can act as a pain reliever when taken as a dietary supplement and that the combination of glucosamine and chondroitin sulfate yields pain relief. Like the evidence offered by Dermal, Naturopathic's evidence provided no basis upon

which a jury could conclude that the chondroitin sulfate in the Joint-Ritis products is present in "pharmacologically effective" amounts to independently act as a pain reliever.

CONCLUSION

It was encumbent upon Dermal to show at trial that chondroitin sulfate, when topically applied, independently relieves pain, and also to show that there was a sufficient amount of chondroitin sulfate in the accused Joint-Ritis products to do so. Viewing the evidence in the light most favorable to the jury's verdict, the parties introduced evidence from which a jury could conclude that: 1. chondroitin sulfate can be absorbed into the body through the skin and 2. the combination of chondroitin sulfate and other ingredients, such as glucosamine or menthol, can act to relieve pain. No reasonable jury could have concluded, based on the evidence presented, that the amount of chondroitin sulfate present in the accused Joint-Ritis products alone relieves pain. Accordingly, because the record contains no proof beyond speculation to support the jury's verdict of infringement, Naturopathic's Motion for JMOL is GRANTED.

IT IS SO ORDERED.

/s/ Gary A. Fenner
GARY A. FENNER, JUDGE
United States District Court

DATED: February 13, 2006